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510(k) Summary

Company Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242

Contact Wendy L. Turner, RAC
Group Manager, Regulatory Affairs
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Date Prepared December 28 , 2005

Device Name Trade Name: CONTOUR® TRANSTAR™ Curved Cutter Stapler Set
Common or Usual Name: Curved Cutter Stapler
Classification Name: Staple, Implantable
[21 CFR 878.4750 (GDW)]

Predicate Devices PROXIMATE® (currently marketed as CONTOUR®) 40mm Curved Cutter Stapler and Reloads
PROXIMATE® HCS Hemorrhoidal Circular Stapler Set

Device Description The CONTOUR® TRANSTAR™ Curved Cutter Stapler is a multifire, single patient use device with a curved head that cuts and staples. The device delivers three staggered rows of titanium staples, with a knife between the first and second row of staples, and creates a 30 mm curved transection. The device is designed with a feature that prevents closing if a used reload or no reload is in the instrument. Another feature is provided to prevent firing unless the closure trigger is latched in the closed position. A retaining pin holds tissue in place and can be positioned either manually or by squeezing the closure trigger. The instrument may be reloaded seven times, for a maximum of eight firings per instrument during a single procedure. Each reload cartridge module includes a knife blade with two staggered rows of staples on the patient side, one staggered row of staples on the specimen side, an anvil, a cutting washer, a retaining pin, a knife guide pin, and a staple retainer. Additional reload cartridges will be available in one size: a green cartridge for compressed tissue with a thickness of 2.0mm.

The CONTOUR® TRANSTAR™ Curved Cutter Stapler is packaged sterile as a single patient use device with two accessories, a Circular Anal Dilator with Obturator and an Access Suture Anoscope. This set is commonly referred to by the product code STR5G.

Indications for Use The CONTOUR® TRANSTAR™ Curved Cutter Stapler and accessories have application for general surgical treatment of anorectal wall defects by means of transanal stapling and resection of mucosal and musculomucosal tissue.

Technological Characteristics The CONTOUR® TRANSTAR™ Curved Cutter Stapler is similar to the design of the predicate device, the PROXIMATE® (or CONTOUR®) 40mm Curved Cutter Stapler. The new device is different from the predicate device in that it produces a 30mm curved staple line.

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Performance Data. Bench testing and preclinical laboratory evaluations were performed to demonstrate that the new device will perform as intended. A clinical literature search was also conducted and the literature supports the intended use of the new device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2006

Ms. Wendy L. Turner, RAC
Group Manager, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K053631
Trade/Device Name: CONTOUR® TRANSTAR™ Curved Cutter Stapler Set
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: December 28, 2005
Received: December 29, 2005

Dear Ms. Turner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

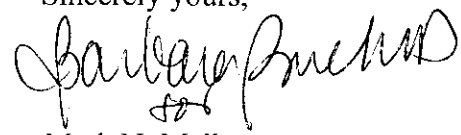
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K053631

Indications for Use

510(k) Number (if known): _____

Device Name: CONTOUR® TRANSTAR™ Curved Cutter Stapler Set

Indications for Use:

The CONTOUR® TRANSTAR™ Curved Cutter Stapler and accessories have application for general surgical treatment of anorectal wall defects by means of transanal stapling and resection of mucosal and musculomucosal tissue.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

(Posted November 13, 2003)

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